AMENDMENT

Amendments to the Claims:

Please amend the claims as follows, without prejudice:

In the Claims:

1. (Original) A suberoylanilide hydroxamic acid (SAHA) Form I characterized by an X-ray diffraction pattern substantially similar to that set forth in Figure 13A.
2. (Currently Amended) A suberoylanilide hydroxamic acid (SAHA) Form I characterized by an X-ray diffraction pattern including characteristic peaks at about 9.0, 9.4, 17.5, 19.4, 20.0, 24.0, 24.4, 24.8, 25.0, 28.0, and 43.3 degrees 2θ, wherein the X-ray diffraction is measured with a Copper X-ray source; and further characterized by a Differential Scanning Calorimetry (DSC) thermogram having a single maximum value at about 164.4±2.0, as measured by a Perkins Elmer DSC 6 Instrument.
3. (Currently Amended) A suberoylanilide hydroxamic acid (SAHA) Form I characterized by an X-ray diffraction pattern including characteristic peaks at about 9.0, 9.4, 17.5, 19.4, 20.0, 24.0, 24.4, 24.8, 25.0, 28.0, 43.3 degrees 2θ, and lacking at least one peak at about <8.7, 10.0-10.2, 13.4-14.0, 15.0-15.2, 17.5-19.0, 20.1-20.3, 21.1-21.3, 22.0.-22.22, 22.7-23.0, 25.0-25.5, 26.0-26.2, and 27.4-27.6 degrees 2θ, wherein the X-ray diffraction is measured with a Copper X-ray source; and further characterized by a Differential Scanning Calorimetry (DSC) thermogram having a single maximum value at about 164.4±2.0, as measured by a Perkins Elmer DSC 6 Instrument.
4. (Original) A suberoylanilide hydroxamic acid (SAHA) Form I characterized by a Differential Scanning Calorimetry (DSC) thermogram having a single maximum value at about 164.4±2.0, as measured by a Perkins Elmer DSC 6 Instrument.
5. (Original) The SAHA Form I according to claim 1, further characterized by a Differential Scanning Calorimetry (DSC) thermogram having a single maximum value at about 164.4 ±2.0, as measured by a Perkins Elmer DSC 6 Instrument.
6. (Cancelled).
7. (Cancelled).

8. (Original) A suberoylanilide hydroxamic acid (SAHA) Form I produced by a purification process comprising the step of recrystallizing a crude preparation of SAHA from an organic solvent or a mixture of an organic solvent and water, with the proviso that the use of acetonitrile alone is excluded.

9. (Currently Amended) The SAHA Form I according to claim 8, further characterized by an X-ray diffraction pattern substantially similar to that set forth in Figure 13A, wherein the X-ray diffraction is measured with a Copper X-ray source.

10. (Currently Amended) The SAHA Form I according to claim 8, further characterized by an X-ray diffraction pattern including characteristic peaks at about 9.0, 9.4, 17.5, 19.4, 20.0, 24.0, 24.4, 24.8, 25.0, 28.0, and 43.3 degrees 2θ, wherein the X-ray diffraction is measured with a Copper X-ray source.

11. (Currently Amended) The SAHA Form I according to claim 8, further characterized by an X-ray diffraction pattern including characteristic peaks at about 9.0, 9.4, 17.5, 19.4, 20.0, 24.0, 24.4, 24.8, 25.0, 28.0, 43.3 degrees 2θ, and lacking at least one peak at about <8.7, 10.0-10.2, 13.4-14.0, 15.0-15.2, 17.5-19.0, 20.1-20.3, 21.1-21.3, 22.0.-22.22, 22.7-23.0, 25.0-25.5, 26.0-26.2, and 27.4-27.6 degrees 2θ, wherein the X-ray diffraction is measured with a Copper X-ray source.

12. (Original) The SAHA Form I according to claim 8, further characterized by a Differential Scanning Calorimetry (DSC) thermogram having a single maximum value at about 164.4±2.0, as measured by a Perkins Elmer DSC 6 Instrument.

13. (Original) The SAHA Form I according to claim 9, further characterized by a Differential Scanning Calorimetry (DSC) thermogram having a single maximum value at about 164.4±2.0, as measured by a Perkins Elmer DSC 6 Instrument.

14. (Original) The SAHA Form I according to claim 10, further characterized by a Differential Scanning Calorimetry (DSC) thermogram having a single maximum value at about 164.4±2.0, as measured by a Perkins Elmer DSC 6 Instrument.

15. (Original) The SAHA Form I according to claim 11, further characterized by a Differential Scanning Calorimetry (DSC) thermogram having a single maximum value at about 164.4±2.0, as measured by a Perkins Elmer DSC 6 Instrument.

16. (Original) The SAHA Form I according to claim 8, wherein said organic solvent is an alcohol.

17. (Original) The SAHA Form I according to claim 16, wherein said alcohol is methanol, ethanol or isopropanol.

18. (Currently Amended) The SAHA Form I according to any one of claims 8, 156 and 157, wherein said purification process comprises the step of recrystallizing said crude SAHA from an organic solvent.

19. (Original) The SAHA Form I according to claim 18, wherein said organic solvent is an alcohol.

20. (Original) The SAHA Form I according to claim 19, wherein said alcohol is methanol, ethanol or isopropanol.

21. (Currently Amended) The SAHA Form I according to any one of claims 8, 156 and 157, wherein said purification process comprises the step of recrystallizing said crude SAHA from a mixture of an organic solvent and water.

22. (Currently Amended) The SAHA Form I according to claim ~~22~~ 21, wherein said organic solvent is an alcohol.

23. (Currently Amended) The SAHA Form I according to claim ~~23~~ 22, wherein said alcohol is methanol, ethanol or isopropanol.

24. (Currently Amended) The SAHA Form I according to claim ~~8~~ 23, wherein said mixture of organic solvent to water comprises about 1-99% ~~organic solvent~~ methanol, ethanol or isopropanol and about 99-1% of water.

25. (Currently Amended) The SAHA Form I according to claim 24, wherein said mixture comprises about 15-85% ~~organic solvent~~ methanol, ethanol or isopropanol and about 1-15% water.

26. (Currently Amended) The SAHA Form I according to claim 24, wherein said mixture comprises about 85% ~~organic solvent~~ methanol, ethanol or isopropanol and about 15% water.

27. (Currently Amended) The SAHA Form I according to any one of claims ~~1-26~~ 1-5 and 8-26, in plate shaped form.

28. (Cancelled).

29. (Cancelled).

30. (Cancelled).

31. (Cancelled).

32. (Cancelled).

33. (Cancelled).

34. (Cancelled).

35. (Cancelled).

36. (Cancelled).

37. (Cancelled).

38. (Cancelled).

39. (Cancelled).

40.-107. (Cancelled)

108. (Withdrawn) A process for preparing a suberoylanilide hydroxamic acid (SAHA) Form I comprising the step of recrystallizing a crude preparation of SAHA from an organic solvent or a mixture of an organic solvent and water, with the proviso that the use of acetonitrile alone is excluded.

109. (Withdrawn; Currently Amended) The process according to any one of claims 108 and ~~159-160~~166-167, wherein said organic solvent is an alcohol.

110. (Withdrawn) The process according to claim 109, wherein said alcohol is methanol, ethanol or isopropanol.

111. (Withdrawn; Currently Amended) The process according to any one of claims 108 and 166-167, wherein said process comprises the step of recrystallizing said crude SAHA from an organic solvent.

112. (Withdrawn) The process according to claim 111, wherein said organic solvent is an alcohol.

113. (Withdrawn) The process according to claim 112, wherein said alcohol is methanol, ethanol or isopropanol.

114. (Withdrawn; Currently Amended) The process according to any one of claims 108 and 166-167, wherein said process comprises the step of recrystallizing said crude SAHA from a mixture of an organic solvent and water.

115. (Withdrawn) The process according to claim 114, wherein said organic solvent is an alcohol.

116. (Withdrawn) The process according to claim 115, wherein said alcohol is methanol, ethanol or isopropanol.

117. (Withdrawn; Currently Amended) The process according to any one of claims 108, 115, 116 and 166-167, wherein said mixture of organic solvent to water comprises about 1-99% of organic solvent and about 99-1% of water.

118. (Withdrawn) The process according to claim 117, wherein said mixture comprises about 15-85% of organic solvent and about 1-15% water.

119. (Withdrawn) The process according to claim 118, wherein said mixture comprises about 85% of organic solvent and about 15% water.

120.-137. (Cancelled).

138. (New) A suberoylanilide hydroxamic acid (SAHA) Form I characterized by an X-ray diffraction pattern including characteristic peaks at about 9.4, 17.5, 19.4, 20.0, 24.0, and 28.0 degrees 2θ, wherein the X-ray diffraction is measured with a Copper X-ray source; and further characterized by a Differential Scanning Calorimetry (DSC) thermogram having a single maximum value at about 164.4±2.0, as measured by a Perkins Elmer DSC 6 Instrument.

139. (New) A suberoylanilide hydroxamic acid (SAHA) Form I characterized by an X-ray diffraction pattern including characteristic peaks at about 9.4, 17.5, 19.4, 20.0, 24.0, and 28.0 degrees 2θ, and lacking peaks at about 13.4-14.0 and 22.7-23.0 degrees 2θ, wherein the X-ray diffraction is measured with a Copper X-ray source.

140. (New) The SAHA Form I according to claim 139, further characterized by a Differential Scanning Calorimetry (DSC) thermogram having a single maximum value at about 164.4±2.0, as measured by a Perkins Elmer DSC 6 Instrument.

141. (New) The SAHA Form I of any one of claims 2-5, 12-15, 138 and 140, wherein the DSC measurement is performed by heating from 50 °C at 10 °C per minute to at least 30°C above the observed melting temperature.

142. (New) The SAHA Form I of claim 141, wherein the DSC measurement is performed with Perkin Elmer standard aluminum DSC sample pans and covers, with a nitrogen gas purge rate at about 20 ml/min.

143. (New) The SAHA Form I according to any one of claims 1-5, 8-17,138-140 and 147-149 that is at least 99.5% pure.

144. (New) The SAHA Form I according to any one of claims 1-5, 8-17, 138-140 and 147-149 that is at least 98% pure.

145. (New) The SAHA Form I according to any one of claims 1-5, 8-17, 138-140 and 147-149 that is at least 95% pure.

146. (New) The SAHA Form I according to any one of claims 1-5 8-17, 138-140 and 147-149 that is substantially free of other polymorphic forms.

147. (New) The SAHA Form I of claim 8, further characterized by an X-ray diffraction pattern including characteristic peaks at about 9.4, 17.5, 19.4, 20.0, 24.0, and 28.0 degrees 2θ, wherein the X-ray diffraction is measured with a Copper X-ray source; and further characterized by a Differential Scanning Calorimetry (DSC) thermogram having a single maximum value at about 164.4±2.0, as measured by a Perkins Elmer DSC 6 Instrument.

148. (New) The SAHA Form I of claim 8, further characterized by an X-ray diffraction pattern including characteristic peaks at about 9.4, 17.5, 19.4, 20.0, 24.0, and 28.0 degrees 2θ, and lacking peaks at about 13.4-14.0 and 22.7-23.0 degrees 2θ, wherein the X-ray diffraction is measured with a Copper X-ray source.

149. (New) The SAHA Form I according to claim 148, further characterized by a Differential Scanning Calorimetry (DSC) thermogram having a single maximum value at about 164.4±2.0, as measured by a Perkins Elmer DSC 6 Instrument.

150. (New) The SAHA Form I of claim 147 or 149, wherein the DSC measurement is performed by heating from 50 °C at 10 °C per minute to at least 30 °C above the observed melting temperature.

151. (New) The SAHA Form I of claim 150, wherein the DSC measurement is performed with Perkin Elmer standard aluminum DSC sample pans and covers, with a nitrogen gas purge rate at about 20 ml/min.

152. (New) The SAHA Form I according to claim 18, wherein said organic solvent is ethanol.

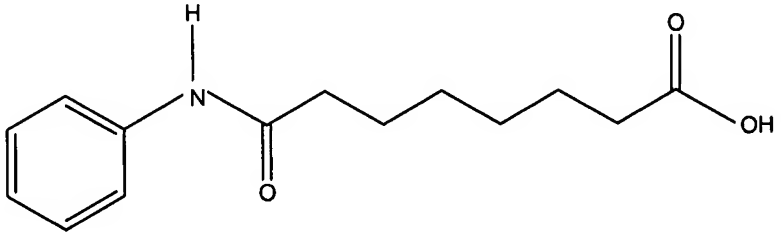
153. (New) The SAHA Form I according to claim 21, wherein said mixture of organic solvent to water comprises about 1-99% ethanol and about 99-1% of water.

154. (New) The SAHA Form I according to claim 21, wherein said mixture comprises about 15-85% ethanol and about 1-15% water.

155. (New) The SAHA Form I according to claim 21, wherein said mixture comprises about 85% ethanol and about 15% water.

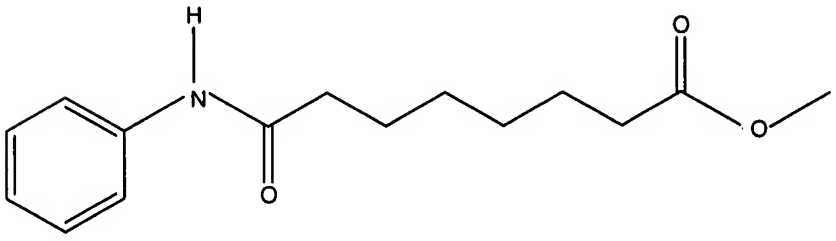
156. (New) The SAHA Form I of claim 8, wherein the crude preparation of SAHA is prepared by:

a. reacting suberic acid with aniline to form suberanilic acid or a salt thereof having the structure:



;

b. reacting suberanilic acid with methanol to form methyl suberanilate having the structure:



;

c. reacting the methyl suberanilate with hydroxylamine hydrochloride to form a crude suberoylanilide hydroxamic acid in a reaction mixture.

157. (New) The SAHA Form I of claim 156, further comprising the steps of:

(1) adding sodium methoxide to the reaction mixture to obtain a clear solution; and

(2) adding glacial acetic acid to the clear solution to form a precipitate comprising crude suberoylanilide hydroxamic acid.

158. (New) The SAHA Form I according to claim 8, that is isolated.

159. (New) The SAHA Form I according to claim 19, that is isolated.

160. (New) The SAHA Form I according to claim 152, that is isolated.

161. (New) The SAHA Form I according to claim 22, that is isolated.

162. (New) The SAHA Form I according to claim 153, that is isolated.

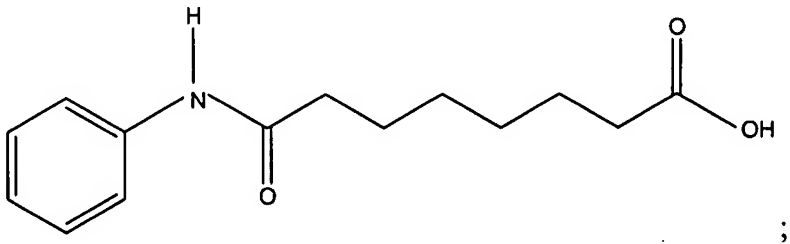
163. (New; Withdrawn) The process according to claim 112, wherein said alcohol is ethanol.

164. (New; Withdrawn) The process according to claim 115, wherein said alcohol is ethanol.

165. (New; Withdrawn) The process according to claim 119, wherein the organic solvent is ethanol.

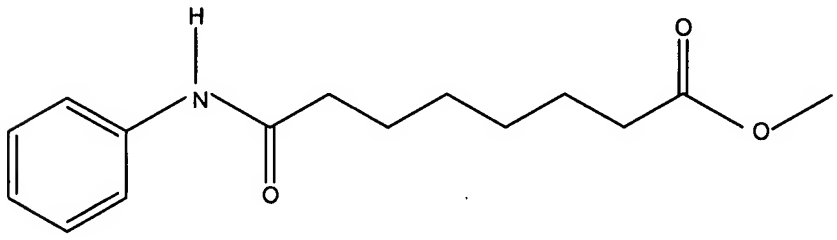
166. (New, Withdrawn) The process of claim 108, wherein the crude preparation of SAHA is prepared by:

a. reacting suberic acid with aniline to form suberanilic acid or a salt thereof having the structure:



;

b. reacting suberanilic acid with methanol to form methyl suberanilate having the structure:



;

c. reacting the methyl suberanilate with hydroxylamine hydrochloride to form a crude suberoylanilide hydroxamic acid in a reaction mixture.

167. (New; Withdrawn) The process of claim 166, further comprising the steps of:

(1) adding sodium methoxide to the reaction mixture to obtain a clear solution; and

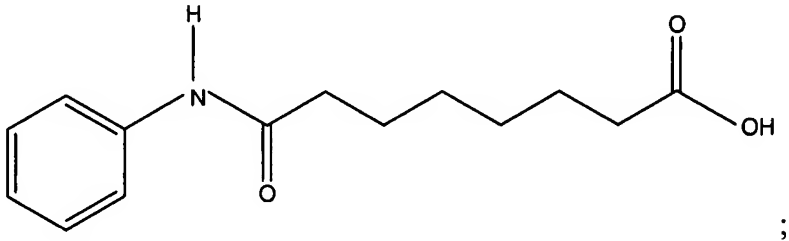
(2) adding glacial acetic acid to the clear solution to form a precipitate comprising crude suberoylanilide hydroxamic acid.

168. (New; Withdrawn) A method for preparing a suberoylanilide hydroxamic acid (SAHA) comprising the step of recrystallizing a crude preparation of SAHA from a mixture of methanol and water.

169. (New; Withdrawn) The method according to claim 168, wherein said mixture of methanol and water is a mixture of about 2:1 of methanol/water.

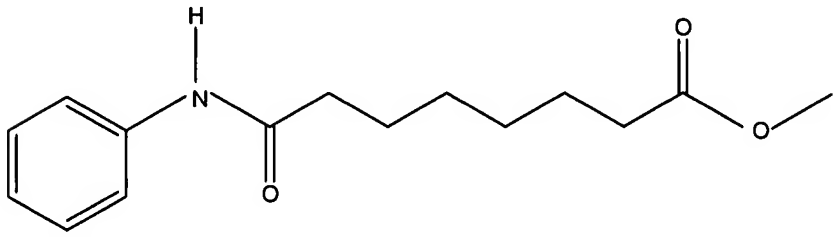
170. (New; Withdrawn) A method for synthesizing suberoylanilide hydroxamic acid (SAHA) comprising the steps of:

a. reacting suberic acid with aniline to form suberanilic acid or a salt thereof having the structure:



;

b. reacting suberanilic acid with methanol to form methyl suberanilate having the structure:



;

c. reacting the methyl suberanilate with hydroxylamine hydrochloride to form a crude suberoylanilide hydroxamic acid in a reaction mixture; and

d. recrystallizing said crude preparation of SAHA from a mixture of methanol and water.

171.(New; Withdrawn) The method according to claim 170, wherein said mixture of methanol and water is a mixture of about 2:1 of methanol/water.

172.(New; Withdrawn) The method according to claim 170, wherein step (c) further comprises the steps of:

(1) adding sodium methoxide to the reaction mixture to obtain a clear solution; and

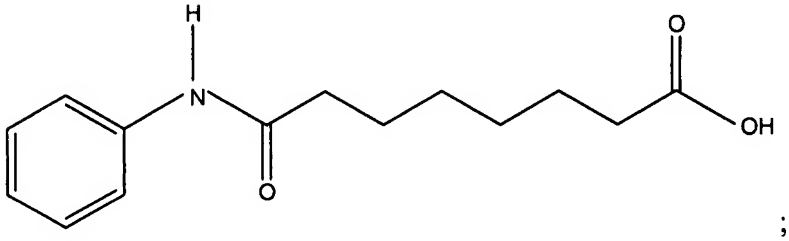
(2) adding glacial acetic acid to the clear solution to form a precipitate comprising crude suberoylanilide hydroxamic acid.

173. (New) A crystalline form of SAHA obtainable by a method comprising the step of recrystallizing a crude preparation of SAHA from a mixture of methanol and water.

174. (New) The crystalline form of SAHA according to claim 173, wherein said mixture of methanol and water is a mixture of about 2:1 of methanol/water.

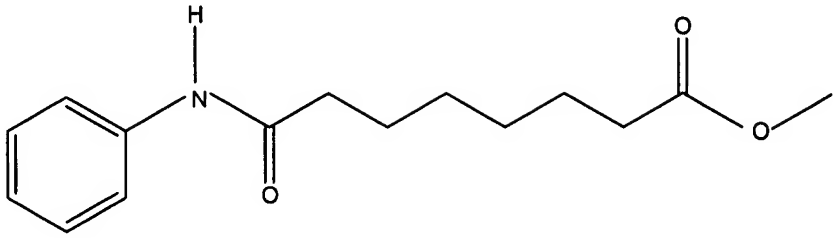
175.(New) A crystalline form of SAHA obtainable by a method comprising the steps of:

a. reacting suberic acid with aniline to form suberanilic acid or a salt thereof having the structure:



;

b. reacting suberanilic acid with methanol to form methyl suberanilate having the structure:



;

c. reacting the methyl suberanilate with hydroxylamine hydrochloride to form a crude suberoylanilide hydroxamic acid in a reaction mixture; and

d. recrystallizing said crude preparation of SAHA from a mixture of methanol and water.

176. (New) The SAHA according to claim 175, wherein said mixture of methanol and water is a mixture of about 2:1 of methanol/water.

177. (New) The crystalline SAHA according to claim 175, wherein step (c) further comprises the steps of:

(1) adding sodium methoxide to the reaction mixture to obtain a clear solution; and

(2) adding glacial acetic acid to the clear solution to form a precipitate comprising crude suberoylanilide hydroxamic acid.

178. (New) The crystalline SAHA of any one of claims 173-177, that is isolated.

179. (New) The SAHA Form I according to claim 19 that is substantially free of other polymorphic forms.

180. (New) The SAHA Form I according to claim 20 that is substantially free of other polymorphic forms.

181. (New) The SAHA Form I according to claim 22 that is substantially free of other polymorphic forms.

182. (New) The SAHA Form I according to claim 23 that is substantially free of other polymorphic forms.